EXHIBIT 4

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July 17, 2018

Via Electronic Mail

Special Master David Cohen
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Re: *In re National Prescription Opiate Litigation*, MDL No. 2804

Dear Special Master Cohen:

I write in reply to Plaintiffs' July 14 submission and in further support of the Manufacturer Defendants' July 11 submission on the June 30 Order. *See* Ex. A, July 11, 2018 D. Welch Letter to Special Master Cohen. In light of your comments on the July 10 conference call that you are thinking anew about the scope and implications of the June 30 ruling, we are surprised at Plaintiffs' insistence that reconsideration is not appropriate and are following up on our prior request for a hearing on reconsideration. By our calculation, if the June 30 Ruling is not reconsidered this week, our 21 day deadline to appeal to Judge Polster would fall on Saturday July 22. Given the importance of this issue, and to ensure that you have ample time to hear and consider the issue, we request a prompt hearing this week, and ask that you also confer with the Court and confirm that Defendants' deadline to appeal with respect to all aspects of the June 30 Ruling is extended for a period of 10 days, until August 1. As we have made clear, the issues we have raised with the June 30 Ruling affect all other phases of discovery and jeopardize the ability of the Manufacturer Defendants to complete document production by the end of August.[1]

Plaintiffs' characterization of the June 30 Ruling as representing the status quo since the beginning of this litigation is contrary to the facts. The previous rulings by the court in the Chicago

[1] Allergan's affidavit concerning the burden associated with the June 30 Ruling is attached as Exhibit B. This burden is exacerbated by Plaintiffs' refusal to work with Allergan in scheduling depositions. *Compare* Pltfs. July 14 Letter at 2 ("Plaintiffs continue to subpoena witnesses because Allergan has refused to identify for Plaintiffs the former employees it actually represents …") *with id.* ("Allergan itself identified each of the ten deponents that Plaintiffs seek to depose as custodians in May . . .").

litigation and Plaintiffs' own complaints belie this characterization. Plaintiffs nonetheless dismiss the burden imposed on the Manufacturer Defendants under the June 30 Ruling because, in their view, Defendants should have been producing this information from the outset. Plaintiffs' assertion that this is a "problem entirely of [Manufacturer Defendant's] own making" is disingenuous. Defendants' productions to date have been consistent with previous judicial orders and comments on the issue. *See* Ex. C, *City of Chicago v. Janssen Pharmaceuticals Inc., et al.*, 1:14-cv-04361, August 21, 2017, Order, Dkt. 603; Ex. D, May 8, 2017 Hearing Tr. at 75:20–76:22.

Further, Defendants' productions were in line with the allegations in the complaints, which do not mention a number of the products covered by the June 30 Ruling. After having already amended on two occasions, Plaintiffs are now trying to rewrite and re-characterize the Track One Complaints. For example, in the July 14 letter, Plaintiffs' cite to a single line Allergan's 2014 10-K for the proposition that Allergan marketed generic drugs. *See* Pltfs. July 14 Letter at 5. This is the first time Plaintiffs cited this 10-K, suggesting that that one vague line in an SEC filing, besides being the first real allegation that Allergan marketed generic drugs, shows that Allergan's generics business was part of a "massive false marketing campaign." *Id.* This is a transparent and limp attempt to add allegations in areas where the complaints were silent.

The Manufacturer Defendants have been operating in good faith to collect and produce documents based on the allegations in the Track One Complaints and consistent with ordered and agreed-to discovery in the Chicago action since the beginning of this litigation; defendants were only able to comply with the expedited schedule in the MDL because of the groundwork completed in the original Chicago case. Some defendants (for example, Mallinckrodt) were not even a party to the Chicago action; Mallinckrodt was only added to the Track One cases by amendment less than three months ago and, therefore, must comply with the court-ordered discovery schedule on a much shorter timeline. The June 30 Ruling puts the Manufacturer Defendants back at square one. Plaintiffs make the unsupported assertion that "Allergan has the resources to complete the project within the allotted time" without understanding (or refusing to acknowledge) the burden of the scope of production ordered in the June 30 Ruling. *See* Pltfs. July 14 Letter at 4.[2] For example, Plaintiffs state that "if Allergan has not promoted Norco for many years, then production of documents regarding Norco should carry little burden." *Id.* That misses the point. Under a strict reading of the June 30 Ruling, Allergan has to produce documents going back to 1996 relating to Norco®, despite the fact that it had not been promoted for many years.

Plaintiffs' letter makes similar misrepresentations in regards to other Manufacturer Defendants. Teva likewise disputes the assertions as to Teva in Plaintiffs' July 14 correspondence.

[2] Plaintiffs similarly provide no factual basis to contradict the burden on Endo from the June 30 Ruling, further detailed in the declaration Endo submitted on July 16, 2018.

First, Teva has not refused to search for and produce documents concerning generics and the Actavis acquisition, as Plaintiffs claim on page 5. To the contrary, Teva has repeatedly advised Plaintiffs that it has undertaken the significant burden of searching for and collecting those documents, and will produce them as soon as it is able. Second, Teva also disputes Plaintiffs' allegations on pages 10-11 of its July 14 letter. Data and materials prior to 2006 are not relevant to any viable claim in this case or proportionate to the case, given the unsupported and bare allegations in the complaints and the applicable statute of limitations. Finally, as to prior productions, Plaintiffs are wrong that, just because information may be "held by parties to this action" that "any burden with regard to recovering it is minimal." July 14 Letter at p. 11. As set forth in the Manufacturers Defendants' earlier submission, there is considerable and potentially insurmountable burden associated with searching for and collecting such materials.

And Plaintiffs' response contains several inaccuracies with respect to Mallinckrodt and appears to ignore entirely Mallinckrodt's position as outlined in the July 13 letter in several respects. For example, Plaintiffs' discussion of Mallinckrodt's search terms is highly misleading. The examples of search terms that Plaintiffs have proposed – regarding the so-called "street names" of Mallinckrodt products and names of "front groups" – were in fact included in Mallinckrodt's search term list. Indeed, a variety of "street names" for Mallinckrodt's drugs were specifically added at the request of Plaintiffs, along with forty other search term strings requested and discussed during the meet and confer process. As detailed in its July 13 letter, Mallinckrodt is applying this expanded list of search terms – which include the names of its generic opioid products—to thirty document custodians.

Contrary to Plaintiffs' assertion, Mallinckrodt discussed at length during the meet and confer process that it finds Plaintiffs' search terms to be exceedingly over-broad, identifying search term strings where it was not even apparent—either to Mallinckrodt or to Plaintiffs—what information the search terms sought to locate that had any relevance to the Track One cases. Moreover, whether documents retrieved by Plaintiffs' search terms are covered in prior productions is a red herring. Mallinckrodt has produced documents pursuant to Paragraph 9(k)(ii) of Case Management Order One regardless of whether they hit on any set of search terms. Most notably, Plaintiffs' complaints about search terms ring especially hollow when compared to the search terms Plaintiffs are themselves applying to their own document collection—which appear to be a single page containing only nine search term strings in total.

Lastly, Plaintiffs' response as to Janssen misstates facts and fails to acknowledge what Janssen has already agreed to produce. Plaintiffs claim Janssen has "ignored request to provide discovery of its Duragesic generic that it licensed to Sandoz." Not so. Janssen has agreed to produce—and has, in fact, already largely produced—information related to the authorized generic fentanyl patch within the files of the 74 custodians and 35 non-custodian sources identified to date. That production should capture all potentially relevant generic-related documents because the

same individuals who managed Duragesic oversaw the relationship with Sandoz—the third party that marketed, sold, and distributed the authorized generic. Additional custodian searches are neither necessary nor proportional to the needs of this case.

Plaintiffs also claim that Janssen has "ignored requests to produce discovery concerning its other Schedule II generics: Ultram, Ultram ER, and Ultracet." This too is not accurate. Ultram, Ultram ER and Ultracet are not, and have never been, Schedule II products. Nor are they generics; they are branded pain relievers. As previously explained in Janssen's June 26, 2018 meet and confer letter to Plaintiffs, Ultram, Ultram ER, and Ultracet were not scheduled until August 18, 2014, at which time the DEA classified these products as Schedule IV.[3] Accordingly, Janssen understands that Ultram, Ultram ER, and Ultracet are not at issue as confirmed by the June 30 ruling, which limits discovery to Schedule II products.

Plaintiffs, notably, do not take issue with Janssen's position as to Tylox—its 34-year-old combination opioid used for the treatment of acute pain. They essentially argue that Janssen's focus on the impropriety of any discovery as to Tylox is an effort to "ignore" Janssen's obligations as to those products that are of genuine interest to Plaintiffs—*i.e.*, Duragesic, the authorized generic fentanyl patch sold by Sandoz, Nucynta, and Nucynta ER. But the discovery record on all of these products belies Plaintiffs' purported concerns. Janssen has substantially completed its productions related to Nucynta and Nucynta ER, has agreed to produce documents related to the generic patch (and has already produced thousands of documents about that relationship), and has produced documents for Duragesic as far back as 1990[4].

The only remaining issue as to Janssen is the temporal scope that is relevant to Duragesic-related documents. Plaintiffs claim that "Janssen has always had the obligation to search for responsive documents . . . dating back to at least 1990." But that, again, is not accurate. Janssen has objected in both its discovery responses and during meet and confers that Plaintiffs' proposed time period is not proportional to the needs of the case, and Janssen has repeatedly asked Plaintiffs to consider a compromise where Janssen produces its regulatory file, including highly relevant NDA files about marketing claims and opioid safety, as far back as 1990, while other document

[3] Janssen previously explained this to Plaintiffs, as reflected in its June 26, 2018 letter to Plaintiffs, which notes "Janssen's three tramadol-based products—Ultram, Ultram ER, and Ultracet—cannot be relevant because those opioids were not even 'scheduled' at the time of the conduct alleged in the complaint. The FDA started to regulate these products as *Schedule IV* opioids on August 18, 2014. Moreover, there are no Schedule IV opioids, regardless of manufacturer, identified in the complaint." (emphasis added).

[4] Janssen has already produced Duragesic's regulatory file in compliance with the June 30 Ruling, which includes the original and supplemental NDAs, periodic safety reports and adverse event reports, marketing materials and scientific studies, annual reports to the FDA, among other things, going back to 1990.

sources, like custodian files, are limited by a reasonable date restriction. Plaintiffs have refused to discuss this offer. While Plaintiffs now claim for the first time that they would consider alternative forms of production, it is impossible to address the sheer logistics of such a request within this letter. Even if Plaintiffs were to review over 3,000 lines of indices and select boxes of potentially relevant information today, the time to collect, process, and review those files would extend beyond the close of fact discovery.

These, of course, are just some of the specific issues bearing on the scope of the June 30 Ruling that the Manufacturer Defendants hope to raise during a hearing on reconsideration. We thus respectfully request that the Special Master reconsider the June 30 Ruling—and seek confirmation that the Court has extended the deadline to appeal all aspects of the June 30 Ruling until August 1, so that these critical issues can be heard and, hopefully resolved in a manner, that obviates the need for appeal.

Sincerely,

/s/ Donna M. Welch
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Re: *In re National Prescription Opiate Litigation*, MDL No. 2804

Dear Special Master Cohen:

As discussed briefly on the discovery teleconference yesterday, I write on behalf of Defendant Allergan Finance, LLC (f/k/a Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc.) ("Allergan") as well as the other Manufacturer Defendants, with respect to your June 30, 2018 Discovery Ruling No. 2 ("June 30 Ruling"). We appreciated your comments during the discovery teleconference yesterday, and your indication that you are thinking anew about the scope and implications of the June 30 Ruling.

Under the current schedule, fact discovery closes on August 31, 2018. The June 30 Ruling, however, has exponentially increased the scope of discovery required to be produced by the Manufacturer Defendants—imposing a significant burden, jeopardizing the August 31 deadline, and endangering our ability to adequately defend our clients' interests. As a threshold matter, discovery under the Federal Rules must be limited in a manner that is proportional to the needs of the case while also considering the burden on the parties. *See* Fed. R. Civ. P. 26(b)(1) ("Parties may obtain discovery regarding any nonprivileged matter that is . . . proportional to the needs of the case, considering . . . the parties' resources . . . and whether the burden or expense of the proposed discovery outweighs its likely benefit.").[1] Further, due process requires that the

[1] Chief Justice John Roberts, "2015 Year–End Report on the Federal Judiciary," Dec. 31, 2015, at 7, *available at* http://www.supremecourt.gov/publicinfo/year-end/2015year-endreport.pdf. (remarking on the amendments to the Federal Rules of Civil Procedure that added the proportionality requirement, "[T]he pretrial process must provide parties with efficient access to what is needed to prove a claim or defense, but eliminate unnecessary or wasteful discovery. The key here is careful and realistic assessment of actual need. . . The amended rules accordingly emphasize the crucial role of federal judges in engaging in early and effective case management.")

Manufacturer Defendants be afforded the ability to conduct discovery sufficient to provide them the opportunity to be heard and to defend against Plaintiffs' claims. *See Grannis v. Ordean*, 234 U.S. 385, 394 (1914) ("The fundamental requisite of due process of law is the opportunity to be heard."); *Mathews v. Eldridge*, 424 U.S. 319, 333 (1976) ("The fundamental requirement of due process is the opportunity to be heard at a meaningful time and in a meaningful manner.") (internal citation omitted).

As the June 30 Ruling acknowledges, the newly-ordered production imposes a significant burden. *See* June 30 Ruling at 8 ("Obviously, the earlier the cut-off for document production, the more burdensome is the discovery request on defendants, and potentially the less relevant."). Despite that burden, Manufacturer Defendants have already begun to undertake significant efforts to comply with the Ruling. And, as described in more detail in Exhibit D to this letter, some Manufacturer Defendants have proposed compromises to Plaintiffs that would comply with the spirit of the Ruling while maintaining August 31 as a realistic deadline. Those proposals (which by nature must be tailored to specific defendants) include, for example, expanding search terms, adding additional custodians, and broadening the applicable date range, among other efforts. Those significant efforts aside, the prejudice to the Manufacturer Defendants in complying, goes well beyond burden.

For example, to date, Allergan has been served with a Rule 30(b)(6) notice of deposition that includes 48 detailed topics (and many detailed sub-topics), and which purports to seek testimony on every opioid product ever sold by Allergan or its predecessors for a period of nearly three decades, even though Allergan no longer owns the vast majority of these opioids and has not marketed others for over a decade.[2]

Plaintiffs also have notified Allergan that they are moving forward with subpoenas/notices of 10 individual witnesses employed or formerly employed by Allergan and have unilaterally issued subpoenas/notices before consulting with Allergan's counsel—notwithstanding the clear requirements of the Court-ordered deposition protocol. *See* Dkt. No. 643 at § I.b ("Absent extraordinary circumstances, counsel for the noticing party should consult in advance with counsel for the deponent in an effort to schedule depositions at mutually convenient times and locations.").[3]

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[2] Plaintiffs originally served a 30(b)(6) notice on Allergan on June 4, 2018. That notice was subsequently amended three times, with the operative notice not being served until July 1, 2018. Although the July 1, 2018 notice raised the number of topics to 48, substantially revised or replaced the earlier topics, and added over 50 new subtopics, Plaintiffs nonetheless complained to the Special Master that they had not yet received a date for testimony. Despite this, Allergan has identified a witness and provided a date for testimony on 31 topics.

[3] Indeed, Plaintiffs served these subpoenas at several witnesses' personal residences without attempting to procure cooperation from Allergan and inappropriately contacted several witnesses who are currently represented or in

Under any standard of reasonableness, these witnesses should not be deposed until custodial files are reviewed and non-privileged documents are produced; while this is well underway, given the breadth of the June 30 Ruling, custodial files likely cannot be produced in full for these witnesses until mid-August or even later.

Nonetheless, Plaintiffs are pushing aggressively for dates for these depositions within the next three weeks. Without relief, given the scope of additional production contemplated by the June 30 Ruling, Allergan will be forced to prepare (as best they can, without sufficient time and documents) witnesses to testify regarding decades of time and multiple products—for which they have only just begun to collect documents and about which there are ***no allegations*** in Plaintiffs' complaints. It is a violation of due process to require Allergan or the other Manufacturer Defendants to prepare and present witnesses before having an opportunity to (1) review these underlying documents and (2) understand the allegations against them.[4] *See Simon v. Craft*, 182 U.S. 427, 436 (1901) ("The essential elements of due process of law are notice and opportunity to defend. In determining whether such rights were denied we are governed by the substance of things, and not by mere form.").

Other Manufacturer Defendants have likewise received sweeping 30(b)(6) and individual deposition notices. As a further example, Plaintiffs served Teva[5] with a Rule 30(b)(6) deposition notice that seeks testimony on 50 extraordinarily broad topics, from five separate corporate entities. Combined with the June 30 Ruling, this Rule 30(b)(6) notice requires Teva to educate a witness or witnesses to testify in detail as to virtually all departments within the various corporate entities—regulatory, compliance, medical affairs, pharmacovigilance, sales, marketing, finance, legal, government affairs, and suspicious order monitoring—going back two decades and concerning more than 20 products. Teva compromised on Plaintiffs' request for documents relating to generics, and Plaintiffs have since disingenuously characterized this compromise as a

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the process of obtaining representation. Allergan is nonetheless in the process of obtaining dates for their depositions.

[4] As discussed on the call today, the prejudice to the Manufacturing Defendants will also be compounded if Plaintiffs are allowed to take depositions now, and then complain that they need additional time with witnesses after documents have been produced. Plaintiffs should be ordered to proceed with depositions of a witness once, after the production of documents and, if they chose to proceed without the benefit of complete productions, they should forgo any additional questioning of defendant witnesses. *See* Dkt. No. 643, Order Establishing Deposition Protocol at Section I f.2 ("Depositions taken in this MDL pursuant to this Order shall not be retaken in this MDL without further order of the court upon good cause shown or an agreement of the parties.")

[5] "Teva" includes Teva Pharmaceuticals USA, Inc., Cephalon, Inc., Watson Laboratories, Inc., Actavis LLC, and Actavis Pharma, Inc. f/k/a Watson Pharma, Inc.

concession that Plaintiffs have stated a claim as to generics. Still, the combination of the expansion of products covered by the request and the newly-ordered time period is entirely untenable.

Mallinckrodt LLC ("Mallinckrodt") likewise was served with a 30(b)(6) notice on July 1, unilateral notices for depositions of six individual fact witnesses, and a request for deposition availability just this past Friday for a seventh individual witness. The June 30 Ruling directly affects Mallinckrodt's ability to schedule and prepare its witnesses for deposition. For example, Plaintiffs have demanded that witness custodial files such as emails be provided based on search terms. However, Plaintiffs have insisted upon a list of over 7,300 words comprising over 200 search strings to date—many of which track the expanded list of products that the June 30 Ruling has encompassed in its scope. That gargantuan list of search terms, combined with the lengthy time period encompassed by the June 30 ruling, multiplies by many times the volume of documents that Mallinckrodt would be required to review. This is particularly true in light of the fact that, as a generics manufacturer, Mallinckrodt sold certain generic product lines decades before any conceivable statute of limitations reference point. That compounded combination of expansive time periods, product lines, and search terms—buoyed by the June 30 Ruling, and sheer document volume—is making it not only burdensome, but practically infeasible, for Mallinckrodt to conform with the Court-ordered fact discovery framework.

Taking a step back, the Track One Plaintiffs allege that demand for opioids was improperly increased by alleged fraud, and by alleged lack of diversion controls. With respect to the first theory of the Track One Complaints, Mallinckrodt has already agreed to provide documents regarding its marketing of opioids generally, as well as regarding Mallinckrodt's opioid products, in accordance with the Track One Plaintiffs' latest proposed definition of the term "Marketing." With respect to the second theory of the Track One Complaints, Mallinckrodt has already agreed to provide documents regarding its opioid diversion controls, including all of the documents that Mallinckrodt previously produced to the DEA in connection with its extensive dedicated investigation of precisely that subject matter. But what appears to have occurred is that these two theories are not translating into a practical set of demanded search terms in light of the June 30 Ruling. For example, there is a wide disconnect between the Track One Plaintiffs' claims and their search terms asking Mallinckrodt to review emails for any and all documents containing the words "Methadose" (an addiction treatment drug) or any other one of Mallinckrodt's 17 listed opioid products or any other manufacturers' opioid product names, on the one hand, and words such as "gorilla" or "aids" or "program" or "report" or "meeting" or "daily" or "sales rep" or "video" or "magazine" or "analysis" or "union" or "nurse" or "duration," on the other hand—anywhere in the document—to give just a small sampling of examples. Mallinckrodt has already provided Plaintiffs with six productions totaling nearly 600,000 pages, with another production set to go out this week, and a further production planned to go out the following week. It is not practical for Mallinckrodt to conform to this expanded discovery framework—while endeavoring to locate, collect, and produce documents while simultaneously preparing witnesses regarding

products and time periods and purported search terms for which the Track One Complaints are entirely and conspicuously silent, including many of Mallinckrodt's generic products sold in the 1990s throughout the United States.

Purdue has also been served with an overly broad 30(b)(6) notice on 50 broad subjects and purporting to cover decades of time, all while Plaintiffs are simultaneously demanding the broad production of tens of millions of pages of discovery. Collecting and reviewing that discovery is part and parcel of the preparations necessary for a 30(b)(6) deposition, and to demand that it occur all at once works unfair prejudice on Purdue's ability to meaningfully prepare its defenses, at the expense of due process. Purdue has nonetheless worked around the clock to produce thus far millions of pages of documents covering broad categories of company departments and substantive subjects.

Endo received a 30(b)(6) notice on July 1 that includes 50 topics, many of which have multiple subparts or are otherwise so broadly described that they constitute multiple discrete topics that should be separately enumerated and counted. Like the notices to other Manufacturer Defendants, the notice to Endo seeks testimony about nearly every aspect of Endo's operations relating to all opioid medications and covers effectively the entire duration of the company's existence. Plaintiffs are demanding that Endo produce witnesses on these topics this month. Doing so is impossible. Indeed, for many topics, producing a witness prior to August 31 is not achievable absent substantial narrowing and clarification by Plaintiffs. Many opioids about which testimony is sought have not been marketed or sold by Endo in years, and given turnover at the company, there are no knowledgeable witnesses readily accessible to Endo. Endo has only begun its investigation into the medications implicated by the June 30 Ruling, many of which are not even mentioned in the Track One complaints and none of which are the subject of substantive allegations.

The substantial prejudice and burden—both relating to collecting, reviewing and producing documents, and then to preparing witnesses to testify regarding such documents—is discussed more specifically below. The burden of these newly-imposed discovery obligations, compounded by the extremely aggressive litigation schedule, deprives defendants of their due process rights. This depravation is particularly disturbing given Plaintiffs' refusal to provide discovery with respect to even the most basic elements of their claims. As just one example, we have never been involved in a case where plaintiffs asserting fraud-based claims have refused even to identify the parties who supposedly received and relied upon the alleged fraud, much less identify what fraudulent statements were made to them and explain their basis for alleging that that fraud caused them harm. We expect to address these truly-extraordinary issues with you shortly with a request for a ruling, but we think this context is important to provide in connection with the instant request.

Scope of Products Subject to Discovery

With only approximately ***60 calendar days*** left of fact discovery, the June 30 Ruling greatly expanded the burden on Manufacturer Defendants to collect, review and produce non-privileged documents regarding products that are not the subject of Plaintiffs' allegations. For example, on its face, the June 30 Ruling requires Allergan to produce documents relating to Norco®—a branded Schedule II opioid that has not been promoted since 2003 and that is not the subject of a single allegation of wrongdoing in Plaintiffs' Track One Complaints.[6] Likewise, the June 30 Ruling could be read to require Allergan to produce documents relating to other Schedule II products that are not even mentioned in the Track One Complaints. Moreover, the June 30 Ruling could be read to include Schedule II generic opioids that Allergan no longer owns (for which the documents, employees and data went to Teva).

Accordingly, compliance with the strict terms of the June 30 Ruling as including all Schedule II opioids (both branded and generic) would require the re-collection and re-review of dozens of non-custodial sources for which collection had already been completed (*e.g.*, the collection of additional hard-copy documents from Iron Mountain). In addition, applying the tens of thousands of search terms Plaintiffs have proposed relating to the other Schedule II opioids would result in millions of documents that would need to be loaded, reviewed and potentially produced. Similarly, strict compliance with the June 30 Ruling would require the re-review of tens if not hundreds of thousands of custodial documents to determine which involve Schedule II opioids that are now within the scope of discovery. Even if Allergan were able to complete this discovery by August 31—which it does not believe is possible—it would be severely prejudiced in its ability to prepare witnesses and to defend itself on the current schedule.

Other Manufacturer Defendants are likewise faced with similar burden and prejudice.[7] For Janssen Pharmaceuticals, Inc., for example, the June 30 Ruling added Tylox to the permissible scope of discovery—a combination opioid from 1984 indicated for acute pain that Janssen discontinued in 2012 after the FDA changed dosing limits on Tylenol, which was a non-opioid component of Tylox. The time and expense of locating, collecting, and reviewing documents from a 34-year-old discontinued product far exceeds any potentially probative value to the allegations in Plaintiffs' complaints. Although it is public knowledge that Janssen manufactured Tylox,

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[6] Indeed, as described in detail in Allergan's June 12, 2018 letter to the Special Master, there are only two references to Norco® in each of the Track One Complaints, and these are merely passing references that "Actavis"—a conglomeration of entities, some of which are no longer affiliated with Allergan—manufactured Norco®. There is not a single allegation relating to misconduct with respect to the marketing or sale of Norco®.

[7] Allergan and the other Manufacturer Defendants will be prepared to submit affidavits supporting the burden associated with compliance, to augment the record.

Plaintiffs chose not to even identify the combination drug after amending their complaint twice. Because of this undoubtedly intentional omission, Janssen long ago planned and organized its discovery efforts around three opioids and not four. It is simply not possible to conduct the same investigation into Tylox and complete any serious discovery effort by the close of fact discovery. To date, Janssen has produced over 500,000 documents relating to Duragesic, Nucynta, Nucynta ER, and opioids generally. An attempt to identify and review Tylox-related materials would be even more complex and time consuming given that Janssen discontinued Tylox six years ago and first marketed the product when computers were in their infancy.

For Mallinckrodt, the June 30 Ruling expands the scope of document collection from the products related to the allegations in the operative amended Track One Complaints (specifically, Exalgo and Xartemis, which are the subjects of the marketing allegations as well as the products underlying the diversion allegations) to ***fifteen*** Schedule II opioid products listed in one paragraph of the Track One Complaint, the majority of which are not mentioned anywhere else. The inclusion of "Methadose" in the scope of discovery is particularly notable—the product is for addiction treatment; it works to prevent opiate effects and decrease the desire to take opiates, and is irrelevant to Plaintiffs claims. Mallinckrodt is currently endeavoring to locate and collect documents related to all fifteen products, but the inclusion of the generics products combined with Plaintiffs' overbroad demands for expansive search terms have created an exponentially larger and ever-expanding universe of documents for Mallinckrodt to locate, collect, review, and produce prior to the Court-ordered fact discovery cutoff of August 31.

For Purdue, the indisputable focus of Plaintiffs' allegations against Purdue concerns OxyContin, and Purdue has thus focused its discovery efforts on OxyContin. Although Purdue initially objected to expanding the scope of discovery to its other products, Purdue agreed as a good faith compromise to expand the scope of its discovery to reach other of its opioid medications, Butrans and Hysingla. Purdue also added other opioid products to its search terms to sweep in additional discovery. Purdue is already being required to re-produce discovery from other litigations, which will include extensive discovery for other of its opioid medications and should be more than sufficient. Purdue has thus already been extremely broad with its approach to discovery and requiring it to go even further is an unworkable extreme that cannot conform to the discovery schedule.

With respect to Endo, strict compliance with the June 30 Ruling would require the inclusion of 13 additional Endo Schedule II opioids, including both branded and generic medications, many of which Endo has not marketed or sold in over a decade. Inclusion of all such Endo opioids for all aspects of discovery is likely to require substantial additional collection of both electronic and hard copy data. Indeed, Plaintiffs have already requested that Endo add twelve *categories* of custodians based on the June 30 Ruling's product scope decision. Simply identifying specific pertinent custodians is itself time-consuming and labor intensive. Particularly given the temporal

scope rulings and the dates during which Endo sold several of the opioids now at issue, there are no employees at the company familiar with Endo's operations as they relate to these many of these medications. As a result, the June 30 Ruling necessitates substantial attorney time simply to investigate sources of information before any collection or review can begin. Further, the June 30 Ruling potentially requires inclusion of all Schedule II generic opioids that have been sold by Endo's generics affiliates, Par Pharmaceutical Inc. and Par Pharmaceutical Companies, Inc. ("Par"), notwithstanding the absence of a single substantive allegation about Par in the Track One Complaints. Adding these products to discovery would likewise necessitate a massive effort to identify, collect, process, review, and produce responsive information regarding medications about which there is not a single specific allegation. The burden on Endo under the compressed discovery schedule is already monumental—Endo currently has well in excess of 150 attorneys working full time to review for production the custodial files Endo had agreed to search for responsive information prior to the June 30 Ruling.

Temporal Scope

The burden and prejudice from including all Schedule II opioids—regardless of whether they are the subject of Plaintiffs' allegations—are compounded by the significant change to the temporal scope of discovery required by the June 30 Ruling. While recognizing that the earlier the start date for production, the more burdensome and potentially less relevant the discovery will be (June 30 Ruling at 8), the June 30 Ruling nonetheless ordered the Manufacturer Defendants to produce documents extending back over two or even three decades on the theory that "[t]he amounts and degree of 'unnecessary prescriptions' and the extent of the 'inappropriate increase' of opioid distribution must be measured against a time before the allegedly wrongful activity began …." It is notable that Plaintiffs, however, have failed to identify a ***single prescription*** for any Schedule II opioid that was written as a result of allegedly fraudulent marketing activity or that was medically "unnecessary" or "inappropriate." *See* Ex. A & B, D. Welch letter dated June 22, 2018, and D. Ackerman response letter dated June 27, 2018; Henry J. Friendly, *Some Kind of Hearing*, 123 U. PA. L. REV. 1267, 1283 (1975) ("There can likewise be no fair dispute over the right to know the nature of the evidence on which the administrator relies."); *Fed. Energy Regulatory Comm'n v. Powhatan Energy Fund, LLC*, 286 F. Supp. 3d 751, 769–70 (E.D. Va. 2017) ("Respondents have not yet had the opportunity to engage in their own independent discovery which, if denied without a knowing and intelligent waiver by Respondents, could implicate their due process right to be heard in a meaningful manner.") (internal citation omitted).

As one example, Allergan appropriately objected to producing documents beyond one year before it acquired and began selling Kadian®, December 2007. As a result of the June 30 Ruling, Allergan is now required to collect and review for potential production documents dating back to 1995 for Kadian® and 1996 for Norco®, as well as transactional data and Suspicious Order reports (if any) dating back to January 1, 1996—expanding the time frame for production by over a decade.

Depending on the production scope as well as any additional search terms or custodial sources or noncustodial sources, this could require the collection and review of hundreds of thousands, if not millions, of additional documents.

Other Manufacturer Defendants likewise face significant burden and associated prejudice from the expansion of the temporal scope of discovery. As another example, for Janssen, the June 30 Ruling will require a culling of at least 2,500 Banker Boxes going back to 1983 for Tylox and 1989 for Duragesic, which could contain upwards of 10,000,000 pages. And this early assessment of burden may expand because Janssen is still attempting to locate and assess information sources connected to Tylox. Janssen's investigation of potentially responsive materials will continue for at least two more weeks, at which time Janssen will still have to scan and review hardcopy documents—pushing document productions related to Tylox and Duragesic past the close of fact discovery. Even if the burden were warranted (and it plainly is not based on the allegations of the Complaint), it simply is not possible to fulfill the newly-imposed discovery obligations for an additional product and a 35-year time period within the short time that remains of the discovery period.

As yet another example, Teva had objected to collecting, reviewing and producing data from prior to 2006. This 12-year period is appropriate, given that the longest statute of limitations potentially applicable to any of Plaintiffs' claims is five years and Plaintiffs' allegations of wrongdoing concern purported conduct that occurred ***after*** January 1, 2006.[8] Because of the June 30 Ruling, Teva now must investigate potentially responsive documents dating back to 1998. Not only does this require Teva to collect, review and produce additional custodial email spanning two decades, but it imposes on Teva the obligation of identifying additional data sources, including paper files and records that are not available electronically, from the late 1990s and early 2000s; locating individuals with knowledge about those data sources, nearly all of whom have left the company many years or even decades ago; exploring whether those sources contain responsive information, likely without the assistance of those who worked with or understood the data sources; and extracting data from those sources which may no longer function properly, have been overwritten, or will generate corrupted or undecipherable data. This undertaking would substantially increase the number of documents that Teva must collect, review, and produce in an already-highly compressed period.

For Mallinckrodt, the June 30 Ruling on temporal scope likewise significantly compounds the burden of the expanded product scope. Mallinckrodt began producing its branded products that are the subject of the Track One Complaints less than a decade ago, and as discussed, it will be providing its Marketing documents for those products and regarding opioids generally.

[8] Only a single paragraph of the 1,000-plus paragraph complaints concern pre-2006 activity.

However, Mallinckrodt started manufacturing generic opioid products in the 1990s. By expanding Mallinckrodt's product scope to generic products for which there are no substantive allegations, the Ruling also more than doubles the number of years at issue. As discussed, Mallinckrodt is agreeing to provide its suspicious order monitoring documents regarding its generic opioid products. However, the Track One Plaintiffs' demanded substantive search terms as applied to Mallinckrodt's documents that concern those generic opioid products goes far beyond. To put that practical burden in context, Mallinckrodt is a 150 year old company and maintains a great deal of hard copy documents at Iron Mountain facilities. It is an enormously burdensome process to search those hard copy records for documents dating back to the 1990s, especially in light of the complete disconnect between Mallinckrodt's generic opioid products during this time frame and any substantive allegations or claims in the Track One Complaints themselves.

For Purdue, expanding the temporal scope of discovery beyond the already very broad scope that Purdue has negotiated is overly burdensome and unworkable. Purdue's business primarily focuses on the research, manufacturing, and selling FDA-approved opioid medications, so to require Purdue to produce decades of documents across the entire company for such a broad topic as "opioid marketing" would be akin to asking a law firm for all documents for its existence related to lawyering. Purdue had already agreed to lift limits to the temporal scope of discovery for many document categories, such as producing all the branded marketing for OxyContin since the product was launched in 1996.

Although the burden on Purdue is already extreme, it becomes nearly impossible—especially under the extremely compressed schedule—when any reasonable limit on temporal scope is lifted for all document categories. Old documents are not available in databases or electronic collections that can be searched but reside in boxes or obsolete systems and archives. For custodial files, Purdue has already offered to go back to 2006, which is a huge burden given how much of the employees' emails and documents relate to opioid medications like OxyContin. Notably, because Purdue is being required to re-produce millions of pages of documents from old discovery from prior litigations, voluminous documents going back to at least the 1990s and likely further will be included, which should be more than sufficient.

As to Endo, prior to the June 30 Ruling, Endo and Plaintiffs reached an agreement that Endo would provide discovery beginning in 2004, two years before the launch of Opana ER, which is the only Endo product subject to substantive allegations in the Track One complaints. As a result of the June 30 Ruling, Plaintiffs now seek discovery from Endo effectively extending back to the company's formation in 1997. As described above, this expanded temporal scope combined with the product scope ruling requires that significant resources be devoted to simply identify and locate sources of potentially responsive information before what is likely to be a significantly burdensome volume of documents and data can be collected, processed, reviewed, or produced. That burden is further compounded by the fact that certain of the potentially responsive documents

are not maintained in easily accessible electronic databases, but rather in boxes of hard copy documents stored off-site organized by individuals no longer with the company.

Especially when combined with the expanded product scope, the dramatically increased temporal scope of discovery not only places an undue and disproportionate burden on the Manufacturer Defendants, but also compromises their ability to prepare witnesses for depositions, including in response to 30(b)(6) notices, on the current schedule.

Prior Productions

The June 30 Ruling also orders the Manufacturer Defendants to produce in the MDL productions made in "*any* prior litigation that involved the marketing or distribution of opioids . . . ." June 30 Ruling at 6. This expands the scope of CMO-1, which required production only of documents produced in prior matters "by federal (including Congressional), state, or local government entities . . . ." On its face, this portion of the June 30 Ruling may not seem overly burdensome, as it requires production of documents already produced elsewhere. However, it requires Defendants' counsel in this MDL—often not counsel for the respective companies in the "prior" litigations or investigations—to investigate whether documents were produced in litigations decades ago, concerning products not even referenced in the complaints, and to resurrect and reproduce those materials in this MDL.

We understand and appreciate that you are continuing to consider this portion of the June 30 Ruling, in connection with your review of the lists of prior production that each defendant has provided. We point out for your consideration, that burden of production aside, there is significant concern about what happens *after* these productions are made. Because of the unprecedented pace of this case, given its breadth and complexity, depositions are happening simultaneously with document collection and production. Defendants do not have adequate time to review the millions of documents from these prior productions, let alone identify documents from these productions that may be relevant to upcoming deponents. This greatly prejudices Defendants' ability to effectively prepare their witnesses, thereby further depriving Defendants of their ability to defend against Plaintiffs' claims.

*** *** ***

Any one of the issues highlighted above imposes unfair prejudice and disproportionate burden on the Manufacturer Defendants. Taken together, this burden and prejudice is compounded greatly at the expense of due process, as it will substantially undermine the Manufacturer Defendants' ability to adequately defend against Plaintiffs' allegations. It is simply impossible to

comply with the June 30 Ruling while maintaining the current schedule.[9] The Manufacturer Defendants therefore request that the June 30 Ruling be reconsidered, and that the ordered production be narrowed appropriately for each defendant. The Manufacturer Defendants request a hearing on reconsideration on or before July 13, so that they can pursue an objection to Judge Polster if needed under Judge Polster's June 4, 2018 Order (*see* Dkt. No. 549) and so that the parties have clarification about the scope and timing of production before depositions begin in earnest.

Sincerely,

/s/ Donna M. Welch
Donna M. Welch
Counsel for Defendant Allergan Finance, LLC (f/k/a Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc.)

cc:
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[9] The June 30 Ruling explicitly provided the parties with an ability "to negotiate different agreements going forward from the requirements set out herein." (June 30 Ruling at 12). Cognizant of your comments on the recent July 3 call scheduled with all parties, Allergan sought to negotiate a solution that would substantially expand its production consistent with the spirit of the June 30 Order, while nonetheless attempting to preserve its ability to complete discovery prior to August 31 and to collect and review documents sufficiently in advance of noticed depositions to adequately defend its interests. *See* Ex. C, D. Welch letter dated July 6, 2018. This compromise position is detailed for Allergan in Exhibit D. Plaintiffs rejected this compromise and insisted on an unrealistic production scope. *See* Ex. E, T. Egler email dated July 10, 2018.

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EXHIBIT B

UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF OHIO EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION	MDL No. 2804 Case No. 17-md-2804 Judge Dan Aaron Polster

DECLARATION OF ALLISON LEE

1. My name is Allison Lee. I am a Senior Project Manager at Epiq.

2. I am assisting Allergan Finance, LLC f/k/a Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc. ("Allergan") and outside counsel Kirkland & Ellis LLP ("Kirkland") in the above captioned MDL. Epiq is Allergan's e-discovery vendor in this action.

3. I submit this declaration in support of Donna Welch's July 11, 2018 letter to Special Master Cohen regarding the June 30, 2018 Discovery Ruling No. 2 ("June 30 Ruling"). The statements herein are based on my personal knowledge or based on my review of documents and discussions with persons involved in Allergan's document production efforts.

Status of Allergan's Discovery Efforts

4. Allergan has made six document productions in this action. To date, Allergan has produced more than 254,000 documents in this matter, including more than 1.48 million pages. Additionally, Allergan is preparing to make a substantial additional production on July 17, with subsequent productions scheduled on a rolling basis through early August.

5. Prior to the June 30 Ruling, I understand from counsel that counsel was aiming to substantially complete Allergan's document production by early August 2018.

Use of Plaintiffs' Proposed Search Terms

6. I understand that Plaintiffs have proposed the use of more than 14,000 additional search terms that include, among others, terms involving generic opioid products.[1]

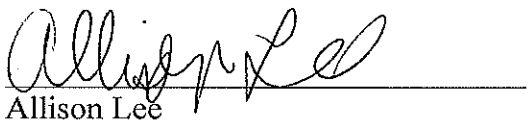
7. To estimate the additional burden of reviewing additional documents, attorneys at Kirkland asked Epiq to run Plaintiffs' proposed search terms across data collected for Allergan to date. The results show that, including full families, these search terms would require promotion into the review database of over 3.7 million additional documents (and likely many more depending on the precise date range applied). Assuming a review rate of 40 documents per hour, this would require tens of thousands of hours of additional attorney time just for first level review. That estimate does not take into account second level privilege review or the creation of privilege logs.

8. Applying Plaintiffs' proposed search terms to the collected documents of the 10 individuals whose depositions I understand from counsel Plaintiffs have requested to date, and removing the front-end date restriction, would result in promotion into the review database of more than 945,000 documents.

9. I declare under penalty of perjury that the statements in this declaration are true to the best of my knowledge and belief.

Dated July 17, 2018

Respectfully submitted,



Allison Lee
Epiq

[1] More specifically, Plaintiffs' proposed terms were sent in two separate lists. One list, titled "Plaintiffs' Proposed Search Terms for Actavis/Allergan Documents," purported to include 216 terms. Many of these entries included the phrase "[list drugs]." The second list included the words to be inserted where "[list drugs]" appears; there are 52 entries on this second list. The result of combining the two lists and properly writing out the terms to be run is more than 14,000 terms.